

REMARKS

Claims 1-38 are pending in this application.

Applicants wish to thank the Examiner for the courtesies extended to their representative during an in-person interview conducted on August 12, 2004. During the interview, a demonstration of the invention was presented to the Examiner. Applicants believe the Examiner recognized from the presentation that the invention is not described in the prior art.

Applicants also thank the Examiner for agreeing that the proposed amendment would overcome the rejection in the last Office Action. The amendments presented here are substantially in accord with what was discussed with the Examiner during the interview by providing more of a context for the entire system claimed. Applicants believe these amendments serve a useful clarification purpose, and are desirable for clarification purposes, independent of patentability. Accordingly, Applicants respectfully submit that the claim amendments do not limit the range of any permissible equivalents.

In particular, claim 1 has been amended to more clearly show that the invention relates to a system of one or more rods disposed externally from the vertebrae by a plurality of fasteners. A slit integrally formed in a rod allows a portion of the rod to have a flexible element that allows limited movement between a first and second vertebra. As seen in several dependent claims, the system can be configured to provide targeted, limited movement in one direction, such as allowing some movement in the anterior-posterior direction, while substantially restricting movement in another direction, such as lateral bending and/or rotation.

Claims 32-38 have been added to further clarify that a plurality of rods may be used, and that more than one rod may have a flexible element integrally formed therein. The newly added claims also are directed toward embodiments where a rod can extend between three or more vertebrae. In one variation of this embodiment, the rod may be capable of substantially stabilizing (i.e., substantially restricting movement between) one pair of vertebrae, while partially stabilizing (i.e., allowing limited movement between) another pair of vertebrae.

As discussed during the interview, the amendment to claim 1 and addition of claims 32-38 are fully supported by the specification. As no new matter has been added, Applicants respectfully request entry of these amendments at this time.

### THE PROVISIONAL DOUBLE PATENTING REJECTION

The Examiner provisionally rejected the claims under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1-59 of copending Application No. 10/443,755. Applicants will provide a terminal disclaimer to overcome this rejection upon confirmation by the Examiner that the pending claims are allowable.

### THE CLAIM REJECTIONS BASED ON LIN '816

The Examiner rejected claims 1-5 and 22-29 as being anticipated by U.S. Patent No. 5,423,816 to Lin for the reasons provided on pages 3-4 of the Office Action. The Examiner then rejected claims 6-21 and 30-31 as obvious over Lin '816.

As discussed during the Interview, Lin '816 does not teach or suggest several features recited in claims. Lin '816 does not describe a spine stabilization system where a plurality of fasteners securely dispose a stabilization rod externally to a first and second vertebra such that a portion of the rod extends between them. Instead, Lin '816 teaches to place a spiral elastic body centrally within the axial line of the vertebrae. See, e.g., Lin '816 at Figure 4. Furthermore, the ultimate objective of the structure of the Lin '816 patent is to achieve new bone growth between two vertebrae so that they are fused together. Lin '816 at col. 1, lines 56-64. This objective is achieved in part by packing the area surrounding the elastic body with bone graft. See, e.g., Lin '816 at col. 4, lines 4-24.

In contrast, the provision of a flexible element integrally formed in the rod of the present invention allows a physician to install the spine stabilization system of the present invention in a manner similar to other external rod systems that are currently only capable of rigidly locking the vertebra in place relative to each other. Instead of rigidly locking the vertebrae in one position, however, the integrally formed flexible element in the rod allows limited relative movement of the vertebrae in one or more directions. In some instances, the limited movement provided by the flexible element can be directed to allow some movement in one direction while substantially restricting it in another. None of these features recited in the pending claims are described or suggested by Lin '816.

In fact, Lin is not directed toward providing limited movement between a first and second vertebra. Instead, Lin teaches to permit the same range of motion of a healthy pair of vertebrae until

the fusion process is completed. Lin '816 at col. 2, lines 36-38. Thus, Lin '816 teaches away from any suggestion to provide limited motion in one or more directions as presently claimed.

Moreover, some of the dependent claims are particularly directed toward systems that provide limited movement in one direction while substantially restricting movement in another direction. See, e.g., dependent claims 33 and 36. Other claims are directed toward particular configurations of the flexible element, the presence of additional integrally formed flexible elements in a rod, the shape or pattern of the slit in the flexible element, or the direction in which two or more slits may travel. These features recited in the dependent claims also are missing from Lin '816. Lin '816 also does not teach a rod having substantially solid end portions as recited, for instance, in dependent claim 3. As discussed during the interview, there are a wide variety of advantages to these embodiments that simply can not be achieved with the structure disclosed in Lin '816.

For at least these reasons, Applicants respectfully submit that, given the clarifying amendment included herein, the rejections based on Lin '816 are now resolved and that the claims are in condition for allowance.


**CONCLUSION**

All claims are believed to be in condition for allowance. If the Examiner believes that the present amendments still do not resolve all of the issues regarding patentability of the pending claims, Applicants invite the Examiner to contact the undersigned attorneys to discuss any remaining issues.

A Fee Sheet Transmittal is submitted herewith to pay for the newly added claims. No other fees are believed to be due at this time.

Respectfully submitted,

Dated: October 13, 2004

By:   
John F. Mulgrew (Registration No. 47,809)  
11012 Langton Arms Court  
Oakton, VA 22124  
(703) 328-5992 Telephone

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